DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR VETERINARY USE

5647. Para-Strep Dust. (F.D.C. No. 41571. S. No. 33-893 P.)

QUANTITY: 15 cases, each containing a total of 175 btls., at Frankford, Del.

SHIPPED: 4-2-58, from W. Caldwell, N.J., by Rockland Chemical Co., Inc.

LABEL IN PART: (Btl.) "Rockland PARA-STREP Dust * * * An Aid in the Treatment of * * * Chronic Respiratory Disease or Air Sac Infection in Chickens * * * Contents equivalent to 25 Grams Dihydrostreptomycin Base and 50 Grams Para-Amino-Benzoic Acid * * * Contents sufficient to treat 1000 chickens."

LIBELED: 5-22-58, Dist. Del.

CHARGE: 502(l)—when shipped, the article purported to be and was represented as a drug composed in part of dihydrostreptomycin, a derivative of streptomycin, and it was not from a batch with respect to which a certificate or release had been issued in accordance with regulations.

DISPOSITION: 10-30-58. Default—destruction.

5648. Bacitracin ointment (veterinary). (F.D.C. No. 41353. S. No. 78-036 M.)

QUANTITY: 335 boxes, each containing 1 syringe, at Lincoln, Nebr.

SHIPPED: 2-21-57, from Inglewood, Calif., by Delta Laboratories.

LABEL IN PART: "Mitox Active Ingredients Per Syringe Bacitracin 3200 Units * * * Veterinarians only * * * Control No. 2175 Expiration Date: Feb. '59."

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less bacitracin than the label declared.

LIBELED: 1-21-58, Dist. Nebr.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 3200 units per syringe; 502(a)—the label statement "Per Syringe Bacitracin 3200 Units" was false and misleading; and 502(l)—the article contained bacitracin, and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 2-7-58. Consent—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5649. Various drugs. (F.D.C. No. 41501. S. Nos. 38-913/20 P, 38-922/4 P.)

QUANTITY: 76,000 *antacid tablets* in btls., 14 1,000-tablet btls. of *salicylamide tablets*, 9 ctns., 12 50-tablet btls. each, of *vaginal tablets*, 22 btls. of *Cholathol capsules*, 44 btls. of *Entrin tablets*, 12 1,000-tablet btls., and 68 100-tablet btls. of *Satinol tablets*, 83 50-tablet btls. of *diethylstilbestrol tablets*, 14 100-capsule btls. of *Quad capsules*, 52 100-tablet btls. of *thyroid tablets*, 18 1,000-capsule btls., and 1 500-capsule btl. of *amobarbital sodium capsules*, at San Francisco, Calif., in possession of Mark Kaplanoff.

SHIPPED: The *antacid tablets*, *salicylamide tablets*, *Satinol tablets*, *Quad capsules*, and *amobarbital sodium capsules* were shipped from Rensselaer, N.Y., by the Delmar Pharmacal Corp., between 6-25-56 and 1-2-58; the *vaginal tablets* were shipped from Portland, Oreg., by Haack Laboratories, Inc., on 6-28-57; and the *Cholathol capsules*, *Entrin tablets*, *diethylstilbestrol tablets*,

and *thyroid tablets* were shipped from Long Island City, N.Y., by Nysco Laboratories, Inc., between 2–19–57 and 12–30–57.

RESULTS OF INVESTIGATION: The *Cholathol capsules, Entrin tablets,* a portion of the *Satinol tablets, diethylstilbestrol tablets, thyroid tablets,* and a portion of the *amobarbital sodium capsules* were repacked after having been shipped in interstate commerce.

LIBELED: 4–10–58, N. Dist. Calif.

CHARGE: *Antacid tablets.* 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use.

Salicylamide tablets. 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use; and 502(f)(2)—the labeling of the article failed to bear adequate warning against misuse by children since its labeling did not bear a statement that the article should be kept out of reach of children.

Vaginal tablets. 502(b)—when shipped, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Cholathol capsules and *Entrin tablets.* 502(b)—the articles, while held for sale, failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(2)—the labels of the articles failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labels of the articles failed to bear adequate directions for use; and 502(f)(2)—the labeling of the *Entrin tablets* failed to bear adequate warning against misuse by children since its label did not bear a statement that the article should be kept out of reach of children.

Satinol tablets (12-btl. lot). 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use; and 502(f)(2)—the article was essentially a laxative, and its labeling failed to bear a warning against use when nausea, vomiting, (stomach sickness), abdominal pain, (stomach ache, cramp, colic), or other symptoms of appendicitis were present, and its labeling also failed to warn that frequent or continued use may result in a dependence upon laxatives to move the bowels.

Satinol tablets (68-btl. lot). 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 502(f)(2)—the article was essentially a laxative, and its labeling failed to bear a warning against use when nausea, vomiting, (stomach sickness), abdominal pain, (stomach ache, cramp, colic), or other symptoms of appendicitis were present, and its labeling also failed to warn that frequent or continued use may result in a dependence upon laxatives to move the bowels.

Diethylstilbestrol tablets. 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer,

packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(f)(1)—the label of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Quad capsules. 502(b)(1)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(d)—the article contained a quantity of amobarbital, a habit forming derivative of barbituric acid, and its label failed to bear in juxtaposition with the statement of the quantity of such derivative in the article the statement "Warning—may be habit forming"; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Thyroid tablets. 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(1)—the label of the article failed to bear the common or usual name of the article; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its labeling failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Amobarbital sodium capsules (3-btl. lot). 502(d)—when shipped, the article contained a quantity of amobarbital, a habit forming derivative of barbituric acid, and its label failed to bear in juxtaposition with the statement of the quantity of such derivative in the article the statement "Warning—may be habit forming"; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Amobarbital sodium capsules (15-btl., and 1 btl. lots). 502(b)(1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(d)—when shipped, the article contained a quantity of amobarbital, a habit forming derivative of barbituric acid, and its label failed to bear in juxtaposition with the statement of the quantity of such derivative in the article the statement "Warning-may be habit forming"; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that a number of vitamin and mineral tablets were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-16-59. Default—the vitamin and mineral capsules were delivered to a charitable institution for its use and not for sale, and the other articles were destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5650. Douche powder. (F.D.C. No. 41427. S. No. 41-182 P.)

QUANTITY: 94 5-oz. jars and 34 12-oz. jars at Seattle, Wash.

*See also No. 5649.